UltraClip II US Wing and Coil
510(k) Summary
21 CFR 807.92.

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As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-379-2836
Fax:	480-449-2546
Contact:	Cindy Moss

2. Subject Device Name:

Device Trade Name:	UltraClip II US Wing and Coil
Common or Usual Name:	Implantable Clip
Classification:	Class II
Classification Panel:	General & Plastic Surgery

3. Predicate Device:

UltraClip II Wing and Coil, K063238, cleared January 30, 2007

4. Summary of Change:

A line extension to provide for the Wing and Clip markers with PVA.

5. Device Description:

The UltraClip II US Wing and Coil are sterile, single use devices comprised of a disposable introducer needle and an implantable metal tissue marker with a polymer insert composed of polyvinyl alcohol (PVA). The device is designed to attach the marker

to soft breast tissue at the surgical site during an open surgical breast at biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

6. Intended Use of Device:

The UltraClip II US Wing and Coil are intended for use to mark a breast biopsy site.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device are identical to those of the predicate device in terms of intended use, indications for use, target population, fundamental scientific technology, operating principle, method of sterilization, packaging configuration, sterility assurance level, and performance characteristics.

8. Conclusions:

The UltraClip II US Wing and Coil met all predetermined acceptance criteria of the design verification and validation testing performed under design controls, and is substantially equivalent to the predicate UltraClip II Wing and Coil.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2009

C.R. Bard, Inc.
% Ms. Cindy Moss
Associate Project Manager
Regulatory Affairs
1625 W. 3rd Street
Tempe, Arizona 85281

Re: K090547
Trade/Device Name: UltraClip II US Wing and Coil
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: February 27, 2009
Received: March 2, 2009

Dear Ms. Moss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

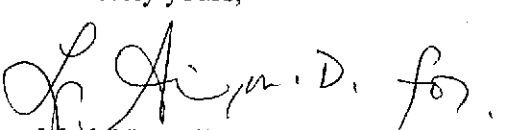
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090547

Device Name: UltraClip II US Wing and Coil

Indications For Use:

The UltraClip II US Wing and Coil are intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM March 16, 2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090547